EXHIBIT B

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

Shari Allen O'Quinn, Bard's Director of Regulatory Affairs (2004-2006)

Deposition Transcript, Oct. 9, 2013 at 55:3-55:14

55:3 Q. How did you educate yourself on the
55:4 IVC filters when you first joined Bard?
55:5 A. I had worked with that branch of the FDA,
55:6 so I was familiar with the general expectations from
55:7 that branch for 510(k)s and PMAs, but specifically on
55:8 the filters, I reviewed their guidance document that
55:9 they have for IVC filters that outlines their
55:10 expectations. I also very frequently referred to the
55:11 SIR guidelines for the reporting standards, and those
55:12 were the two documents that I referred to most
55:13 frequently that were specifically related to the

Allen O'Quinn at 60:9-61:10

60:9 You also knew that there were a significant
60:10 number of fractures being reported at that time --
60:11 MR. LERNER: Objection to --
60:12 BY MR. LOPEZ:
60:13 Q. -- of the device. Correct?
60:14 MR. LERNER: Objection to form.
60:15 THE WITNESS: I would say
60:16 significant -- we were aware of the events that
60:17 were being reported, and monitoring them to ensure
60:18 that they were within the range that was acceptable
60:19 in the SIR guidelines.
60:20 BY MR. LOPEZ:

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

60:21 Q. Acceptable to the SIR guidelines?
60:22 A. (No audible response.)
60:23 Q. Okay. How about acceptable to physicians
60:24 and patients that were getting the device, did you
60:25 ever do any surveys about that to determine whether
61:1 or not they thought that what was being reported to
61:2 you was acceptable to them to have your device
61:3 implanted in them?
61:4 MR. LERNER: Objection to form; also vague
61:5 as to time period.
61:6 THE WITNESS: We -- at many different times
61:7 while I was at Bard, we worked closely with
61:8 physicians to ask them for input on the product and
61:9 the performance, and to help us understand and
61:10 investigate these events.

Allen O'Quinn at 99:14-100:21

99:14 Q. Well, okay. What's the
99:15 different performance profile for the Recovery versus
99:16 a Simon Nitinol as a permanent device?
99:17 A. Is that I can't -- I don't recall the
99:18 rates of events that were reported, but we would
99:19 have to look at some of the documents --
99:20 Q. Well, what do you mean --
99:21 A. -- that show --
99:22 Q. -- by performance profile, the different --
99:23 A. Because --

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

99:24 Q. -- they had different performance profiles?
99:25 A. Well, we talk -- what I was talking about
100:1 was as -- once the devices are commercially
100:2 available, events that occur are reported to us, and
100:3 we look at those events and look at the rates of
100:4 those events, and certain products have different
100:5 rates of events than others. And even if products
100:6 are substantially equivalent, like Recovery and
100:7 Simon Nitinol, they may have -- one may have slightly
100:8 higher rates in one criteria, and others may have
100:9 slightly higher rates in other criteria.
100:10 And that's why I use the terms performance
100:11 and criteria, is that depending on the product, there
100:12 may be different rates for each event that's
100:13 reported, but we monitor, are those rates below the
100:14 ranges that's expected for those kinds of products.
100:15 And that maintains that they're still substantially
100:16 equivalent.
100:17 Q. Well, expected by whom?
100:18 A. By clinicians that have determined these
100:19 guidelines. We refer to the SIR guidelines for those
100:20 rates, and FDA also referred to that document to know
100:21 what were acceptable rates.

Allen O'Quinn at102:2-102:12

102:2 Q. Now, if there's a threshold --
102:3 whatever this SIR threshold is, or acceptance is, are

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

102:4 you saying that the doctors don't care whether or not
102:5 the device is at the high or low end of the
102:6 threshold? They don't care about that when they're
102:7 making a decision on whether or not to use someone's
102:8 device?
102:9 A. They need to know what the risks are, and
102:10 they need to know that -- and as a company, we're
102:11 being responsible to make sure that those rates are
102:12 within acceptable ranges.

Allen O'Quinn at176:16-178:13

176:16 Q. Okay. Now, my question is
176:17 specifically, as you were evaluating the performance
176:18 of the Recovery device and comparing it to the
176:19 performance of the predicate device, Simon Nitinol
176:20 Filter, was there a certain threshold of injuries and
176:21 deaths and complications that the company would say
176:22 is too many for us to continue to market and sell the
176:23 Recovery device as a safer and better device than the
176:24 Simon Nitinol Filter?
176:25 A. Yes, but those guidelines are based
177:1 upon the SIR guidelines. That's how -- we don't --
177:2 can't --
177:3 Q. No.
177:4 A. -- just make those numbers up. They have
177:5 to be --
177:6 Q. Okay.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

177:7 A. -- have clinical foundation, and that was
177:8 the clinical foundation --
177:9 Q. So it --
177:10 A. -- that we based the thresholds.
177:11 Q. So it didn't matter whether or not
177:12 the Recovery Filter caused 25 times more -- there
177:13 were 25 times more migrations with the Recovery
177:14 Filter than there were the Simon Nitinol Filter, as
177:15 long as that 25 times greater than the Simon Nitinol
177:16 Filter was within these guidelines you're talking
177:17 about, it was okay to continue to market and sell the
177:18 Recovery; is that --
177:19 A. But --
177:20 Q. -- right?
177:21 MR. LERNER: Objection --
177:22 BY MR. LOPEZ:
177:23 Q. Is that right --
177:24 MR. LERNER: -- to form.
177:25 BY MR. LOPEZ:
178:1 Q. -- ma'am?
178:2 A. 25 times more, it depends on what that rate
178:3 is. Are you talking about 1 in 500 million versus --
178:4 Q. That --
178:5 A. -- 1 in --
178:6 Q. That's my point.
178:7 A. -- 100?
178:8 Q. It doesn't matter to me.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

178:9 A. That's why I can't answer the
178:10 question based upon 25 times without looking at what
178:11 were the rates and are those --
178:12 Q. That's what I just said.
178:13 A. -- acceptable rates.

Allen O'Quinn at 228:2-228:8

228:2 Q. Did the Recovery Filter have expected or
228:3 estimated failure rates once it was being implanted
228:4 in human beings?
228:5 A. Estimated failure rates?
228:6 Q. Yeah.
228:7 A. The rates that I'm familiar with are those
228:8 that were in the SIR guidelines.

Brett Baird, Bard's Senior Product Manager (2007) and Marketing Manager (2008 – 2011)

Deposition Transcript, June 9, 2016 at165:6-165:21

165:6 Q. Okay. Do you know anything about whether
165:7 or not Bard was using the SIR guidelines as a tool
165:8 to -- to arm sales reps with as a way to promote the
165:9 safety profile of the filters?
165:10 A. I don't know what was sent out as
165:11 promotion. I do know that as a company we definitely
165:12 looked at SIR guidelines as an important thing to
165:13 look at for complication rates.
165:14 Q. Okay. Why?

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

165:15 A. It shows specific rates over a long,
165:16 expansive period of time. SIR is -- was the
165:17 governing body of the group of customers of ours,
165:18 interventional radiologists. So it's the Society of
165:19 Interventional Radiologists. So this is -- these are
165:20 their guidelines. This is what they look to for
165:21 safety and complication rates.

Baird at 250:8-250:25

250:8 Q. You say "The important thing is not to
250:9 overreact"?
250:10 A. Correct.
250:11 Q. Those are your words. Right?
250:12 A. Yes.
250:13 Q. About a study that's potentially involves
250:14 your product where people are dying. Correct?
250:15 A. About a single center unpublished study.
250:16 There are a number of other studies presented,
250:17 showing lower fracture rates. Again, remembering, we
250:18 capture all of the fractures. We capture everything,
250:19 not a single center, but all. And those are the
250:20 rates that we need to focus on. The things that
250:21 instead of overreacting to one specific study, we
250:22 need to look at overall the data set that shows that
250:23 overall the filter fractures and other experiences
250:24 with the filter complications are well under the SIR
250:25 guidelines.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

280:16 Q. At the same time do you know if sales reps
280:17 would tell physicians, look, we consider a 0 to 41
280:18 percent penetration rate acceptable for our filters?
280:19 MR. CONDO: Object to the form. Asked and
280:20 answered.
280:21 THE WITNESS: I think I answered that
280:22 already. Can you say it again?
280:23 MR. SCHULTZ: Sure.
280:24 Can you read the question back, please.
280:25 (Record read.)
281:1 THE WITNESS: Yeah, I don't know what the
281:2 salesperson would say. I stated before we use the
281:3 SIR guidelines as a benchmark to be able to show that
281:4 we are well within parameters of what's accepted by
281:5 the SIR foundation or group.

Baird at 386:25-387:22

386:25 Q. So my question to you, and you can take the
387:1 time you need, is I would like for you to look
387:2 through these SIR guidelines and tell me anywhere in
387:3 these guidelines that it suggests that Table 2, the
387:4 reported incidences of trackable adverse events, is
387:5 meant to provide manufacturers with a range of
387:6 acceptable complication rates.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

387:7 A. Well, I'm sure it doesn't say it because
387:8 this is addressed to the clinicians.
387:9 Q. Precisely. So you agree with me there's
387:10 nothing in the SIR guidelines that suggest the
387:11 purpose behind Table 2 is to provide Bard a range
387:12 that it should consider an appropriate range for
387:13 adverse events at any given time? Do we agree on
387:14 that?
387:15 MR. CONDO: Could you read the question
387:16 back, please.
387:17 (Record read.)
387:18 THE WITNESS: Yeah, a journal will never
387:19 address a manufacturer.
387:20 BY MR. SCHULTZ:
387:21 Q. Okay.
387:22 A. That's not the vehicle for it.

<u>Andrzej Chanduszko, Bard's Senior Engineer, R&D Staff Engineer (2004-2014)</u>

Deposition Transcript, Oct. 10, 2013 at 48:11-49:5

48:11 Were you aware that that
48:12 perforation through the vena cava could potentially
48:13 cause death?
48:14 A. Probably not.
48:15 Q. Probably not?
48:16 What do you base that on?
48:17 A. Just my recollection.
48:18 Q. You probably weren't aware of it or it

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

48:19 probably couldn't cause death?
48:20 A. I'm not a medical professional. So if, as
48:21 I sit here today, I think it would be very unlikely.
48:22 Q. Based on what?
48:23 A. Based on what I know and what I remember.
48:24 Q. About what?
48:25 A. About penetrations.
49:1 Q. Okay. What do you base that on?
49:2 A. Generally speaking, that penetrations, if
49:3 you take the SIR guidelines, for example, generally
49:4 speaking, they -- they're not considered
49:5 life-threatening.

John DeFord, Bard's V.P of Science and Technology (2004-2007)

Deposition Transcript, June 2, 2016 at 338:8-338:18

338:8 Q. Wasn't he trying to --
338:9 wasn't he trying to deviate from the SRI
338:10 (sic) guidelines that Bard had attempted
338:11 to utilize to determine what to call a
338:12 serious adverse event or not?
338:13 A. You know, I don't remember
338:14 all the specifics there. I think that
338:15 Dr. Lehmann -- my recollection is that he
338:16 was not using the SIR guidelines as they
338:17 were intended and so, again, there was a
338:18 dispute about that.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

DeFord at 111:17-114:6

111:17 Q And you are comparing the reports of events --
111:18 correct? -- to physicians' advice of events going way
111:19 back to early times when the filters were first
111:20 introduced; correct?
111:21 A I'm comparing our performance to what the end
111:22 user, the authority, says this is the standard in which
111:23 filters will be measured.
111:24 Q Where in the Society for Interventional
111:25 Radiology articles does it say that that is the
112:1 standard by which filters should be measured?
112:2 A They are the SIR guidelines.
112:3 Q There is no document that's called an SIR
112:4 guideline; correct?
112:5 A I don't know. As near as I know, there is.
112:6 Q You have -- really? You have the SIR
112:7 guideline?
112:8 A I do not.
112:9 Q You had a document called the SIR guidelines?
112:10 A What I can tell you is the Society of
112:11 Interventional Radiology, Society of Vascular Surgery,
112:12 all societies have guidelines that they provide their
112:13 discipline, their society. Performance criteria.
112:14 Q And the guidelines -- there are guidelines
112:15 that are actually called guidelines --
112:16 A I --
112:17 Q -- that report on performance?

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

112:18 A I don't know if that's the vocabulary they
112:19 use, but they have rates in which -- that you as a
112:20 clinician should expect, in this case an IVC filter, to
112:21 perform, whether it's caval occlusions or migrations.
112:22 Their standards are established through the literature
112:23 over time.
112:24 Q And are you aware that the SIR article that
112:25 you are relying upon as of December 2004 was actually a
113:1 study that was published and a study that was written
113:2 by Dr. Clement Grassi, among others?
113:3 A Sounds correct. He was a thought leader and
113:4 early adopter of the procedures.
113:5 Q And are you aware that Dr. Grassi was deposed
113:6 in this litigation?
113:7 A No, I was not.
113:8 Q And were you aware -- so then you were not
113:9 aware that Dr. Grassi said the SIR article that you are
113:10 referring to, the piece of medical literature, was
113:11 indeed not a guideline?
113:12 A No. I don't know what he refers to it as.
113:13 Q So you don't know one way or the other?
113:14 A I don't know what Dr. Grassi's opinion is, no.
113:15 Q And do you even know if that's the article
113:16 that you are referring to as a guideline?
113:17 A I don't know. I don't know what he was
113:18 referring to.
113:19 Q So what -- where are the guidelines that you

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

113:20 were referring to as the head of sales in
113:21 December 2004?
113:22 A I'm referring to those -- to answer your
113:23 question, those were -- those were the guidelines that
113:24 were -- there was very -- there needs to be -- for
113:25 performance awareness, there needs to be standards of
114:1 product performance. Each society has general
114:2 agreements on what those standards look like.
114:3 Q And you are saying that the Society for
114:4 Interventional Radiology wrote these standards; is that
114:5 right?
114:6 A Yes.

DeFord at 239:10-241:17

239:10 During your deposition, did you give some
239:11 testimony about what you called SIR or SIR guidelines?
239:12 A I did.
239:13 Q And what's your understanding of what they
239:14 are?
239:15 A They are -- the SIR provides guidelines on
239:16 overall expectations of certain procedures in terms of
239:17 performance rates or expected -- or potential failure
239:18 rates, just as importantly.
239:19 Q Okay. And in the title of this document does
239:20 it contain the word "guidelines"?
239:21 A It does.
239:22 Q And do you recall in your deposition there

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

239:23 being some dispute as to whether what the -- what is
239:24 published by the Society of Interventional Radiologists
239:25 is actually guidelines?
240:1 A Yes.
240:2 Q And does it say that right in the title?
240:3 A "Quality Improvement Guidelines for
240:4 Percutaneous Permanent Inferior Vena Cava" -- yes.
240:5 Q All right. And if you would flip over with me
240:6 to the third page.
240:7 A Uh-huh.
240:8 Q Down at the bottom center, there is a heading
240:9 there that reads "Complications." Do you see that?
240:10 A I do.
240:11 Q All right. If you would just read along with
240:12 me, I'm going to read it into the record.
240:13 Under Complications, it says:
240:14 "Each currently available filter
240:15 has been studied extensively as part of
240:16 the Food & Drug Administration approval
240:17 process. Few comparative studies have
240:18 been completed evaluating all filters in
240:19 one project, and those that have done so
240:20 have been retrospective analyses.
240:21 Complication rates are highly variable
240:22 depending on the filter being studied.
240:23 For simplicity, these guidelines will
240:24 not suggest threshold rates for each

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

240:25 individual filter. Rather, filtration
241:1 devices will be considered as group."
241:2 Did I read that correctly?
241:3 A Yes.
241:4 Q Okay. And then does it refer you over to
241:5 Table 1?
241:6 A It does, yes.
241:7 Q And what does Table 1 set forth?
241:8 A Complications of reported death rate,
241:9 percentages, recurring PE, IVC filter occlusion, filter
241:10 embolization, and access site thrombosis.
241:11 Q And does the document also set forth a word
241:12 there called "threshold"?
241:13 A Yes.
241:14 Q And what is the threshold that is -- as you
241:15 would interpret it?
241:16 A The threshold for death rate complications is
241:17 roughly 1 percent.

Robert DeLeon, Bard's Western Regional Manager (2006-2007)

Deposition Transcript, June 16, 2016 at 90:24-91:25

90:24 Do you see where it says, "Latest JVIR,
90:25 critical information, read"?
91:1 A. Yes.
91:2 Q. And again, this is addressed to you as well
91:3 as others, from Jason.
91:4 "Attached is an extremely significant

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

91:5 edition of JVIR, where the guidelines for the
91:6 treatment of DVT-VTD and the associated use of
91:7 permanent and optional IVC filters are laid out,
91:8 carrying this information in your detail bag would be
91:9 no different than a professional golfer carrying the
91:10 USGA rules, golf rules, with them. It is imperative
91:11 that we know the SIR guidelines on IVC filters."
91:12 Do you see that?
91:13 A. I do see it.
91:14 Q. Okay. So Jason thinks this is imperative to
91:15 know. Does this help refresh your recollection at
91:16 all about what these are?
91:17 A. It does now, sir.
91:18 Q. Okay. And what are they?
91:19 A. They're guidelines for the use of permanent
91:20 and optional filters.
91:21 Q. Okay. Guidelines for whom?
91:22 A. For physicians.
91:23 Q. Okay. Were they guidelines for
91:24 manufacturers?
91:25 A. I don't know.

David Feigal, Bard's Regulatory Expert

Deposition Transcript, May 21, 2015 at 53:2-53:15

53:2 Q. So you're not saying that the studies show
53:3 the failure rates are low. You are just saying that
53:4 the studies don't prove that they are high.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

53:5 A. No. Maybe I'm -- maybe I'm just not being
53:6 straightforward enough.
53:7 Many of these studies can't establish rates
53:8 at all. The ones that do have reports of numerators
53:9 and denominators have rates that I consider rates
53:10 that are similar to the ones that, for example, the
53:11 SKIVER [phonetic] professional society says that
53:12 they think what these rates are.
53:13 Q. Okay. Are you talking about the SIR
53:14 guidelines document?
53:15 A. Yes.

Feigal at 57:5-58:18

57:5 Q. Okay. So you have raised a number of
57:6 concerns about the reliability of the reports that
57:7 you looked at in this document. Right?
57:8 A. Yes.
57:9 Q. So if those same concerns existed with the
57:10 reports or medical literature on which the SIR
57:11 guidelines are based, wouldn't you also discount
57:12 those findings?
57:13 A. Yes, I would. I would say that those
57:14 would -- excuse me -- those would suffer from the
57:15 same limitations.
57:16 Q. Okay. So, for example, if that 10 percent
57:17 number was based on a single center study of 20
57:18 devices, do you think that's reliable?

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

57:19 A. No.
57:20 Q. Do you think you should know that before
57:21 you make opinions about what the known failure rates
57:22 were for fracture?
57:23 A. Well, I don't think we know the known
57:24 failure rates. You know, there are, there are
57:25 estimates, actually, in the Morales paper from FDA.
58:1 You know, they're -- I think there hasn't been a
58:2 study that actually can determine them, but I think
58:3 we know from the prospective series that these rates
58:4 are not, are not common. These are not things that
58:5 are occurring in most of the patients who get these
58:6 products. So, you know, that's our -- that's our
58:7 basic problem is that there aren't methods that
58:8 actually tell us what those rates are with enough
58:9 precision to compare products or to compare products
58:10 even over time.
58:11 Q. But the manufacturers internally can at
58:12 least develop cumulative proportional failure rates
58:13 based off their sales data and at least the reported
58:14 failure rates to them. Right?
58:15 A. Um, they can, they can do that. They can
58:16 compare the reports that they've had to date and
58:17 sales that they've had to date. Yes, they could do
58:18 that.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

Timothy Fischer, Bard's expert

Deposition Transcript, March 29, 2017 at 246:3-247:21

246:3 Q. So on occasion doctors in Wisconsin asked
246:4 you questions or bring up the -- the SIR guidelines
246:5 relating to IVC filters?
246:6 A. They would, especially once --
246:7 MR. O'CONNOR: Form, foundation. Excuse
246:8 me.
246:9 THE WITNESS: Sorry. Especially once
246:10 competitive reps started pulling out stuff about
246:11 the MAUDE database and putting numbers in front of
246:12 them, that's when they really started going back
246:13 to, okay, show me the clinical information, you
246:14 know, let's talk about the clinical documents
246:15 and --
246:16 BY MR. LERNER:
246:17 Q. When you look at, if you go to the
246:18 page S273, other trackable events, this -- this
246:19 guideline that was provided by SIR in 2001 and
246:20 reprinted in 2003, what is the reported rates for
246:21 penetration, IVF penetration?
246:22 MR. O'CONNOR: Form and foundation.
246:23 THE WITNESS: So this is a compilation of
246:24 a whole bunch of clinical papers, and it says zero
246:25 to 41 percent.
247:1 MR. O'CONNOR: Form.
247:2 BY MR. LERNER:

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

247:3 Q. In any of the documents that Mr. O'Connor
247:4 showed you today, did you find any documents that
247:5 suggested that Bard's IVC filters penetrated at
247:6 rates that exceeded those reported rates --
247:7 MR. O'CONNOR: Form and foundation.
247:8 BY MR. LERNER:
247:9 Q. -- of penetration?
247:10 A. I didn't see any, no.
247:11 Q. In reviewing all the documents today, did
247:12 you see anything that suggests that Bard's internal
247:13 rates for migration exceeded the reported rates of
247:14 zero to 18 percent?
247:15 A. No, I didn't.
247:16 Q. And then for filter fracture did you see
247:17 anything within the documents that you were shown
247:18 today that the reported rates of between two and
247:19 ten percent for filter fracture in this article
247:20 were exceeded?
247:21 A. No.

Clement Grassi, M.D., Bard's Radiology Consultant

Deposition Transcript, July 30, 2014 at133:20-134:24

133:20 Q. Well, what if after the company
133:21 investigated thoroughly and determined that their
133:22 device was migrating and causing deaths four or
133:23 five times greater than any other device on the
133:24 market, and they knew that it was -- that there

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

was a design problem with their device in having these events occur, and instead of telling doctors or FDA or anyone else that, they represented that their device was just like every other device because they fell within the SIR guidelines for death --

MS. DALY: Object --

Q. -- would that be an appropriate representation made by the company or an appropriate use of your SIR guidelines?

MS. DALY: Object to the form and to the hypothetical. Go ahead.

A. Well, in --

Q. Sir, would it be appropriate or not?

A. Again, I'll try to answer your question as accurate as I can. Our SIR guidelines were designed for physicians and practitioners and to help them in an educational and instructive fashion and for those who are involved with IVC filter placements, and one would hope, of course, that complications, serious ones such as you've explained, would be reported, duly noted, and processed in a conscientious fashion.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

97:1 Q When you talked about thresholds, you talked
97:2 about them in the context of my question about migration
97:3 and other things. The guidelines don't actually have
97:4 thresholds --
97:5 A For those, for fractures and migration, right.
97:6 They give you a range. This enormous range.
97:7 Q Right. So there are no thresholds under the
97:8 guidelines for migration, correct?
97:9 A Correct. I was --
97:10 Q There are no thresholds for fracture, correct,
97:11 under the guidelines?
97:12 A Correct.

John Kaufman, M.D., Bard's Consultant

Deposition Transcript, Jan. 4, 2017 at 97:1-97:12

102:9 The SIR guidelines are for doctors and they're
102:10 not for manufacturers, correct?
102:11 A They are for physicians. They're clinical
102:12 practice documents, standards documents for clinical
102:13 practice.
102:14 Q And they're not for manufacturers?
102:15 A Unless it states there are some guidelines that
102:16 give -- unless they state that in the guidelines, these
102:17 are design specifications, they would not be meant for
102:18 that. And they would state that in the guidelines.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

William Little, Bard's V.P. of Global Marketing (2008-2011)

Deposition Transcript, July 27, 2016 at 392:1-393:14

392:1 It's just a report of the historical nature of
392:2 some of the reports in the literature about a
392:3 variety of IVC filters.
392:4 A No. That's not what guidelines are. Guidelines
392:5 are not a report about some of the literature
392:6 that are out there. That's wildly different.
392:7 When you're talking about guidelines from a
392:8 society, that is the highest level document that
392:9 they have. It's not just some amalgamation of
392:10 some data.
392:11 Q Is that how Bard measured whether or not their
392:12 device was performing at an expected or
392:13 acceptable range with respect to their
392:14 complications?
392:15 A Guidelines would be an input, but a quality
392:16 system -- and I'm sure you could talk to the
392:17 quality folks specifically about how our quality
392:18 system worked, but we worked within the quality
392:19 system to trend complaint analyses.
392:20 Q No, but my question was: Was Bard using --
392:21 whatever was in the guidelines, whether you call
392:22 it a threshold or reported rate, that as long as
392:23 your devices were within a threshold or
392:24 reporting rate, that your devices were
392:25 performing in a manner in which physicians would

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

393:1 accept them to perform?
393:2 A That's not how Bard measured their quality
393:3 system.
393:4 Q Okay. I didn't think so.
393:5 And that would be inappropriate for them to
393:6 do that, right?
393:7 A It would be an input. You certainly would
393:8 consider guidelines when you're thinking about
393:9 your own complaint rates, but it wouldn't be the
393:10 only way. And, no, it wouldn't be
393:11 inappropriate. It would be appropriate to
393:12 consider guidelines when you're thinking about
393:13 your own complaint rates. You should consider
393:14 that.

Chad Modra, Bard's V.P. Quality Assurance (2011 – 2014), V.P. of Operations (2014 – present)

Deposition Transcript, Jan. 20, 2016 at 521:10-523:13

521:10 Q. So have you -- have you done comparative
521:11 analysis among all your filters to see how -- whether
521:12 or not these new designs are actually improving the
521:13 type of trending of injuries and deaths and other
521:14 malfunctions?
521:15 A. On failure modes and -- yes.
521:16 Q. Things are getting better as you go?
521:17 MR. NORTH: Objection to the form.
521:18 THE WITNESS: They're all still below the

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

521:19 SIR guidelines.
521:20 BY MR. LOPEZ:
521:21 Q. Why do you mean the SRI [sic] guidelines?
521:22 What does that have to do with whether or not a
521:23 device is performing as expected and intended?
521:24 A. And they're also all below our FMEA --
521:25 Q. Well, I know, but what do the SRI
522:1 guidelines have to do with whether or not your device
522:2 is performing as safely and effectively as expected
522:3 or intended to perform?
522:4 A. It's a benchmark --
522:5 Q. Well, no, it's not.
522:6 A. -- the industry has set out, and also our
522:7 internal FMEAs.
522:8 Q. Which --
522:9 MR. NORTH: Objection to the form.
522:10 Argumentative.
522:11 BY MR. LOPEZ:
522:12 Q. Well, wait a minute, the industry has set
522:13 that out as a benchmark for safety and effectiveness?
522:14 A. They've published that as an understanding
522:15 of the known rates of complications related to the --
522:16 Q. Well, no, the known rates of complications
522:17 going -- citing articles from the 1980s and 1990s.
522:18 That's what the SRI guidelines do. Right?
522:19 A. I don't know.
522:20 Q. You've never read it?

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

522:21 A. I've read the guidelines --

522:22 Q. Okay.

522:23 A. -- but I haven't read each and every

522:24 citation, no.

522:25 Q. But the guidelines have nothing to do with

523:1 whether or not your company is selling a device that

523:2 is as safe and as effective as is expected and

523:3 intended to perform?

523:4 A. It's one input to our risk management

523:5 system to understand the rates of failure of these

523:6 class of devices.

523:7 Q. These class of devices, there were no

523:8 retrievable devices, and it involved devices that

523:9 have long been off the market that are cited in the

523:10 SRI guidelines. Right?

523:11 MR. NORTH: Objection to the form.

523:12 THE WITNESS: I'm not in a position to

523:13 question the SIR guidelines.

<u>Daniel Orms, Bard's Regional Sale Manager (2008 – 2012), District Manager (2003-2008), Field Manager (1997 -2001)</u>

Deposition Transcript, Aug. 16, 2016 at 177:13-179:3

177:13 if Bard is aware of problems that are

177:14 outside of the reporting guidelines, yes, that's what --

177:15 I would want to know that.

177:16 Q. If they're aware of trends with tilting that

177:17 are causing harm to patients or potential harm, that's

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

177:18 something you would expect them to advise you,
177:19 correct?
177:20 A. Again, if it's --
177:21 MR. BROWN: Object to form.
177:22 A. If it's outside of the guidelines. Because I
177:23 think that's the -- to your point, I had -- I won't do
177:24 that you because you'll wind up striking me. I had
178:1 physicians ask me the same question that you asked me
178:2 many times.
178:3 Q. And you want to be open and you want to be
178:4 honest.
178:5 A. And I answered exactly the way I just told you,
178:6 and I said as far as I know they're well within the SIR
178:7 guidelines.
178:8 Q. Okay.
178:9 A. And the physicians were happy. That was all
178:10 they wanted to know.
178:11 Q. But today you learned about a lot more events
178:12 than you ever were aware of.
178:13 A. But my understanding is that, again, my
178:14 understanding is that it's still well within the SIR
178:15 guidelines for adverse events, for all of those adverse
178:16 events that you just described.
178:17 Q. But can we leave this just with the agreement
178:18 you would want to know about the tracking and trending
178:19 of events in your sales department.
178:20 A. Yes.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

178:21 Q. And that would be information you would like
178:22 to know in the event you needed to communicate it to a
178:23 physician for whatever reason, correct?
178:24 A. If -- if it was outside the guidelines, if it
179:1 was significant and the data was reliable and it was
179:2 something that the physician could use to make an
179:3 informed decision, then I would like to know.

Ann Roberts, M.D., Plaintiff's Expert

Deposition Transcript, July 7, 2017 at 270:2-270:11

270:2 Q Dr. Roberts, are you aware of any
270:3 medical literature finding a rate of migration for
270:4 Bard Recovery or G2 filter higher than 25 percent?
270:5 A Any literature -- published literature?
270:6 I'm not sure.
270:7 Q Are you aware of any internal Bard
270:8 document showing a rate of migration for the
270:9 Recovery or G2 filter anywhere near 25 percent?
270:10 A I don't think it was higher than
270:11 25 percent.

Kim Romney, Bard's Senior Product Manager (2011 to present)

Deposition Transcript, Sept. 7, 2016 at 192:5-192:13

192:5 Are
192:6 you aware if these are to be utilized as guidelines
192:7 for manufacturers and their reported failure rates?
192:8 MR. LERNER: Objection to form. Outside

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

192:9 the scope of the notice.
192:10 THE WITNESS: As our guidelines for
192:11 reported failure rates?
192:12 Q. BY MR. GOLDENBERG: Yes.
192:13 A. No, they're not.

S. William Stavropoulos, M.D., Bard's Consultant

Deposition Transcript, Feb. 22, 2017 at 254:1-255:11

254:1 Q. When you use IVC filters in
254:2 your practice, do you use them with the
254:3 understanding that they can carry the
254:4 ranges of risk identified in the SIR
254:5 guidelines?
254:6 MR. MATTHEWS: Object to the
254:7 form.
254:8 THE WITNESS: I understand
254:9 that there are risks and discuss those
254:10 risks with the patients. As far as
254:11 the -- what -- and I guess, what was
254:12 your specific question regarding any
254:13 more than that?
254:14 BY MR. BROWN:
254:15 Q. If you look at Table 2,
254:16 there are ranges of reported risks --
254:17 A. Right.
254:18 Q. -- for individual
254:19 complications like IVC penetration,

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

254:20 filter fracture, migration and other
254:21 complications, which include tilt of the
254:22 filter more than 15 degrees from the IVC
254:23 axis.
254:24 And my question is, when you
255:1 use IVC filters and when you think about
255:2 the risks associated with IVC filters,
255:3 are you thinking in terms of the rates of
255:4 risk that are reported in the SIR
255:5 guidelines?
255:6 MR. MATTHEWS: Object to the
255:7 form.
255:8 BY MR. BROWN:
255:9 Q. For IVC filters generally?
255:10 A. For -- in these ranges, this
255:11 is part of what I'm thinking about, yes.

Stavropoulos at 281:21-282:13

281:21 Q. You were asked questions
281:22 about an IVC focus group. I believe it's
281:23 Exhibit 13.
281:24 A. Yes.
282:1 Q. And there was a notation in
282:2 this document about a statement that was
282:3 ascribed to you about 1 in 1,000 as far
282:4 as fracture being high?
282:5 A. Yes.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

282:6 Q. Sitting here today, do you
282:7 remember saying that?
282:8 A. I don't.
282:9 Q. And as discussed in the SIR
282:10 guidelines from 2001, the reported rate
282:11 for fracture for IVC filters generally
282:12 was up to 10 percent; is that right?
282:13 A. Yes.

Jack Sullivan, South Regional Manager (2005), Central Regional Manager (2006 - 2009), Western Regional Manager (2010 -20111)

Deposition Transcript, Sept. 16, 2016 at 120:16-121:19

120:16 Q. So here you've got the associate
120:17 product manager for IVC filters from Bard sending
120:18 an email to sales personnel telling them to use
120:19 the SIR guidelines as comparison points for
120:20 reported rates with physicians; is that right?
120:21 MS. KOWALZYK: Object to the form.
120:22 A. So it's -- I guess what she's saying
120:23 is she points out some different percentages, and
120:24 she just says, keep these in mind when you're
120:25 discussing clinical studies and filter
121:1 complications. So, yeah.
121:2 MS. KOWALZYK: Object to the --
121:3 Q. BY MR. DeGREEFF: But she's talking
121:4 about keeping the SIR guidelines in mind; right?
121:5 A. Sure. Yes.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

121:6 Q. And that the SIR guidelines provide
121:7 definitions and benchmarks for IVC filter
121:8 performance?
121:9 A. That's what it says, yes.
121:10 Q. And the sales force are the people who
121:11 will be communicating with physicians; right?
121:12 A. Yes.
121:13 Q. And, in fact, she's telling them to
121:14 use this information with physicians?
121:15 A. She's saying to keep it in mind.
121:16 Q. Well, and she's telling them to use
121:17 it. "Use the reported rates as comparison
121:18 points"; right?
121:19 A. Fair to say, yes.

Sullivan at 231:13-232:11

231:13 I'm going to ask you: As you sit here
231:14 looking at this, how can you reconcile these
231:15 numbers with the representations that were made
231:16 about the G2 having increased fracture resistance?
231:17 MS. KOWALZYK: Object to the form.
231:18 A. Again, I don't know that I can -- I
231:19 don't know that I can reconcile it. I don't know
231:20 what's behind it. I don't know what's -- for
231:21 example, what the SIR guidelines are and what
231:22 folks that need to make this decision felt was a
231:23 threshold that they needed to maintain.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

231:24 Q. BY MR. DeGREEFF: What do the SIR
231:25 guidelines have to do with this document right
232:1 here?
232:2 A. Well, as we kind of go back to, I
232:3 think, our original questioning, filter fracture
232:4 is a known complication for vena cava filters. So
232:5 we know fractures -- filters fracture. All
232:6 filters fracture. None of them are perfect.
232:7 So it would appear in this slide that
232:8 Recoveries may fracture more than Simon Nitinol,
232:9 but as an overall percentage, where does that fall
232:10 in line as acceptable or unacceptable; I don't
232:11 know.

Sullivan at 231:13-232:11

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Exhibit B – Testimony from Bard's employees use of SIR Guidelines

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232:8 Recoveries may fracture more than Simon Nitinol,
232:9 but as an overall percentage, where does that fall
232:10 in line as acceptable or unacceptable; I don't
232:11 know.

Natalie Wong, Senior Quality Engineer, New Product Development (2004 – 2007), Quality Engineering Manager (2008 -2011)

Deposition Transcript, Oct. 18, 2016 at 127:4-129:13

127:4 Q. And let me ask you something, the first
127:5 bullet says, "Complication/trackable event rates from
127:6 SIR guidelines (all filters) is 2 to 10 percent."
127:7 Did I read that correctly?
127:8 A. Yes.
127:9 Q. What is the relevance of the SIR guidelines
127:10 to -- to fracture rates with -- with the Recovery and
127:11 G2 and SNF?
127:12 A. It was a -- it was a document stating what
127:13 the thresholds or rates that were accepted by the SIR
127:14 group.

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

127:15 Q. Well, do you know -- do you know what
127:16 filters the SIR guidelines considered in -- in this
127:17 publication?
127:18 A. No.
127:19 Q. Have you ever looked at the studies relied
127:20 on in the SIR guidelines?
127:21 A. I read the document, but I don't recall the
127:22 details.
127:23 Q. And is it your understanding that -- that
127:24 the SIR guidelines were providing a threshold for
127:25 fracture rates?
128:1 A. Yes.
128:2 Q. Okay. And are you aware of any of the --
128:3 the testimony from various members of Bard and the
128:4 drafter of the SIR guidelines, stating that it
128:5 doesn't establish a threshold?
128:6 A. That I don't know.
128:7 Q. No one ever provided you those depositions?
128:8 A. No.
128:9 Q. So based on this -- well, strike that.
128:10 Was it -- was the SIR guidelines commonly
128:11 used as a threshold within Bard?
128:12 A. Not as a threshold, but it was used to
128:13 compare what our rates are against it.
128:14 Q. So 2 to 10 percent would mean that it would
128:15 be an acceptable threshold for up to 10 out of 100
128:16 filters to fail, to fracture?

Exhibit B – Testimony from Bard's employees use of SIR Guidelines

128:17 A. I don't think that was acceptable to us.
128:18 Q. Okay. Well, that -- you're using it as a
128:19 threshold here. Right?
128:20 A. No.
128:21 Q. What was acceptable to -- to Bard, based on
128:22 the --
128:23 A. It would be against the DFMEA.
128:24 Q. Okay.
128:25 A. And the R002 procedure.
129:1 Q. So, if this -- so if this is not an
129:2 acceptable rate then why is it being used -- why is
129:3 it included here as -- why is it relevant?
129:4 A. It's a comparison.
129:5 Q. Why compare something you don't think is
129:6 acceptable?
129:7 A. It was accepted by industry for the SIR
129:8 guidelines. We were just comparing our numbers to
129:9 what those rates were in that article.
129:10 Q. Did -- but so this rate was not acceptable
129:11 to Bard?
129:12 A. No, it was something we compared, we looked
129:13 at it against.